

This Safety Data sheet is not intended for consumers and does not address consumer use of the product. For information regarding consumer applications of this product, refer to the product labeling.

1. PRODUCT & COMPANY IDENTIFICATION

Product Name: Prax® Lotion

Product Use: Local anesthetic

Manufacturer: Ferndale Laboratories, Inc.
780 West Eight Mile Road
Ferndale, Michigan 48220-2498

Emergency Telephone: For emergency involving spill, leak, fire exposure or accident, call CHEMTREC (800) 424-9300, day or night

Product Technical and Medical Information: (800) 621-6003

2. HAZARDS IDENTIFICATION

Hazard Classification: Not classified

Emergency Overview- Irritant

Causes numbing effect to skin and respiratory tract. Adverse effects may include numbness, burning, redness, itching, hives, or large hive-like swellings on the skin or in the mouth or throat. May cause allergic reaction if ingested, or in contact with skin.

Potential Health Effects

Eye Contact: May cause irritation.

Skin Contact: Repeated or prolonged contact may cause irritation.

Ingestion: May cause abdominal cramps and diarrhea.



National Fire Protection Association (NFPA)
(estimated)

Health-2 Flamambility-1 Reactivity-0

3. COMPOSITION/HAZARDOUS INGREDIENTS

Chemical Name	CAS Number	Percent (by weight)	Exposure Limits in Air (8 hr. TWA)
White Mineral Oil, Heavy	8042-47-5	<10%	No Limit
Pramoxine Hydrochloride	637-58-1	1%	Not Established
Stearic Acid	57-11-4	<10%	OSHA PEL: 5 mg/m ³ ACGIH TLV: 3 mg/m ³
Cetyl Alcohol	36653-82-4	<5%	Not Established
Forlan-L: Petrolatum Lanolin Hydrogenated Coconut Oil Sorbitan Sesquioleate	8009-03-8 8006-54-0 84836-98-6 8007-43-0	<5%	Not Established

Stearyl Alcohol Cetyl Alcohol	112-92-5 36653-82-4		
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Listed Carcinogens: The following components, present at concentrations of $\geq 0.1\%$ are listed as carcinogens or potential carcinogens by either the National Toxicology Program (NTP), the International Agency for Research on Cancer (IARC), OSHA or ACGIH: None.

4. FIRST AID MEASURES

- Eyes:** Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention immediately. Continue to rinse.
- Skin:** Flush skin thoroughly with soap and water. Get medical attention if symptoms persist or occur after washing.
- Ingestion:** Wash out mouth with water if conscious. Do NOT induce vomiting. May act as a laxative. Get medical attention.

5. FIRE FIGHTING

- Flammable Properties:** During a fire, gases hazardous to health may be formed.
- Flash Point:** $> 235^{\circ}\text{F} / 113^{\circ}\text{C}$
- Extinguishing Media:** Do NOT direct a solid stream of water or foam into burning molten material; this may cause spattering and spread the fire. Suitable extinguishing media: CO_2 , foam, dry chemical or water spray.
- Special Fire Fighting Procedures:** Self-contained breathing apparatus and full protective clothing should be worn when fighting chemical fires.

6. ACCIDENTAL RELEASE MEASURES

- Personal Protection:** Use personal protection recommended in Section 8 of the MSDS.
- Spill Cleanup Methods:** Cover with inert, absorbent material and remove to disposal container. Spill area may be slippery. Flush with plenty of water.

7. HANDLING AND STORAGE

- Handling:** Store at controlled room temperature between $59\text{--}86^{\circ}\text{F}$ ($15\text{--}30^{\circ}\text{C}$).

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- Engineering Controls:** Not applicable.
- Respiratory Protection:** Not applicable; aerosol formation is extremely unlikely.
- Eye Protection:** None required during normal administration or use of Prax® Lotion. When handling large quantities, use approved eye protection to safeguard against potential eye contact.
- Protective Clothing:** Prolonged skin contact may require protective gloves.
- Hygienic Work Practices:** Wash hands thoroughly after handling. If working with large quantities of the lotion (such as spill clean-up), use chemical resistant gloves and appropriate eye protection. No eating, drinking or smoking in area.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	White creamy lotion
Odor:	Slight
Odor threshold:	Not Available
pH:	Not Available
Melting point/freezing point:	Not Available
Initial boiling point and boiling range:	Not Available
Flash point:	> 235°F / 113°C
Evaporation rate:	Not Available
Upper/lower flammability or explosive limits:	Not Available
Vapor pressure:	Not Available
Vapor density:	Not Available
Relative density:	Not Available
Solubility (ies):	Not Available
Partition coefficient: (-octanol/water)	Not Available
Auto-ignition temperature:	Not Available
Decomposition temperature:	Not Available
Viscosity:	Not Available

10. STABILITY AND REACTIVITY

Stability:	Stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.
Conditions to avoid:	Avoid high temperatures and all sources of ignition.
Materials to avoid:	Avoid contact with strong oxidizing agents and strong acids.
Hazardous Decomposition Products:	Combustion can yield carbon dioxide, carbon monoxide, and other oxides. Partial combustion also forms carbon monoxide, soot, aldehydes, and ketones.
Hazardous Polymerization:	Will not occur.

11. TOXICOLOGICAL INFORMATION**LD50/LC50:**

Pramoxine hydrochloride:

- Oral: LD50 = 1050 mg/kg (rat)

Stearic Acid:

- Skin Rabbit LD50: > 5000 mg/kg
- Oral: LD50 > 4600 mg/kg (rat)

Cetyl Alcohol:

- Oral: LD50 > 20,000 mg/kg (rat)

Mineral Oil:

- Dermal: LD50 > 2000 mg/kg (rabbit)
- Oral: LD50 > 5000 mg/kg (rat)

12. ECOLOGICAL INFORMATION

There is no ecological information available at this time. Prevent spilled material from entering sewers, storm drains, other unauthorized drainage systems, and natural waterways.

13. DISPOSAL RECOMMENDATIONS

This product is not hazardous waste when disposed of. For small quantities, discard in a municipal landfill as ordinary trash. For large quantities, any disposal practice must be in compliance with local, state, and federal laws and regulations (contact local or state environmental agency for specific rules). Do not dispose of via sinks, drains, or into immediate environment.

14. TRANSPORT INFORMATION

This product is not a hazardous material for DOT, IATA, IMO or TDG shipment.

15. REGULATORY INFORMATION

TSCA: Exempt

CERCLA: This product contains no components subject to reporting or notification requirements.

SARA Title III: Exempt

16. OTHER INFORMATION

Date Issued: January 19, 2016

Supersedes Date: April 9, 2015

SDS: 0748, Prax® Lotion

Revision Changes: Updated Section 11 Toxicological Information as per updated SDS for Pramoxine Hydrochloride 07-Apr-2015, Stearic Acid 04-Jun-2014, Cetyl Alcohol 08/05/2014, Mineral Oil 01/20/2016

Notice: The preceding information is based on available data compiled by the manufacturer from its own studies and the work of others and is believed to be correct. However, no warranty is expressed or implied as to the accuracy, completeness or adequacy of this information, the results to be obtained from the use thereof or the hazards connected with the use of the material. Since the information contained herein may be applied under conditions beyond our control and with which we may be unfamiliar, Ferndale Laboratories, Inc. does not assume any responsibility for the results of its use. The information is furnished upon the condition that the persons receiving it shall make their own determination as to the suitability of the product for their particular use.